REMARKS

Reconsideration of this application, as amended, is respectfully requested.

A new abstract is provided.

Claims 13-18 and 22-28 were under 35 U.S.C. §112, second paragraph as allegedly indefinite for lacking antecedent basis for :the opening." This has been corrected.

Claims 13-18 and 22-28 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Gautier in view of Burstein. Applicants respectfully traverse.

Burstein has a filing date of October 7, 1999. Certified English translations of the priority German applications are enclosed, and it is respectfully submitted that DE 199 33 206.1 has an earlier filing date than Burstein, i.e., July 15, 1999, and that Applicants are entitled to this date under 35 U.S.C. §119. Particular attention is attention is drawn to page 2, item 2.4 which teaches that, as an option, the cross section may be oval. Thus, the rejection should be withdrawn, as Burstein is not available as a reference.

In any event, Burstein discloses in Figs. 6 and 7 a plastic bearing 760 which is placed in an intermediate shell 740. This intermediate shell 740 is inserted with a tenon 610 into the metal shell 720. In the present application, a bearing shell 1 of ceramic is surrounded by a plastic jacket 2 which in turn is inserted into a metal shell (not shown). A tenon to improve the resistance to rotation is disposed not on the intermediate shell 740 as in Burstein, but is arranged on the antifriction shell 1. In other words, the resistance to rotation of the antifriction shell 1 in plastic jacket 2 is improved.

Thus, the combination of cited references cannot lead one skilled in the art to the claimed invention. Accordingly, the rejection should be withdrawn.

Any fees due that are not provided herewith may be charged to deposit account no. 50-0624.

Respectfully submitted,

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OIPE JC14
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PATENT & TRADEMARK OFFICE

VERIFICATION OF TRANSLATION

I, Lesley Marion Scarborough, of Redcliff Quay, 120 Redcliff Street, Bristol, England, am conversant with both the English and German languages and I state that, to the best of my knowledge and belief, the following is a true and correct translation of the official copy of the documents in respect of a patent application filed in Germany on the 15th July 1999 under Serial Number 199 33 206.1 and of the official certificate attached thereto.

Signature of translator L.M. Scarborough

Dated this 3rd day of November 2003

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FEDERAL REPUBLIC OF GERMANY

Certificate of priority relating to the filing of a patent application

Serial Number: 199 33 206.1

Date of filing: 15th July 1999

Applicant/holder: CeramTec AG Innovative Ceramic Engineering, Plochingen/DE

Title: Ceramic sandwich insert for an artificial hip joint

IPC: A 61 F 2/34

The attached copies are a correct and exact reproduction of the original documents of this patent application.

(*Seal*)

Munich, the 19th July 2000
On behalf of the President of
the German Patent and Trademark
Office
(*Signature*)
Faust

Ceramic sandwich insert for an artificial hip joint

1. Prior art and the disadvantages thereof:

In the case of artificial hip joints it is possible that the ball-head shaft will strike against the acetabulum time and time again. If the impact forces are sufficiently great, this can result in the mechanical acetabulum-composite breaking up. In particular, sandwich socket systems are at risk here, since the PE that is predominantly used can only put up insufficient resistance against these forces of impact.

Systems used:

1.1 Ceramic insert, around which injection-moulding is effected, with recesses (Sulzer Patent Application EP 0 726 066 A2)
- 1.1.1 Inferior PE strength properties as a result of heating of the PE
- 1.1.2 Thermal shock for ceramic insert
- 1.1.3 Outlay on injection-moulding on account of injection mould and handling of the hot portions
- 1.1.4 Large amount of construction space required

1.2 Conical clamping of the ceramic insert in PE
- 1.2.1 To some extent instances of low composite-component strength
- 1.2.2 Large amount of construction space required

1.3 Pressing spherical ceramic insert into PE in the warm state

1.3.1 To some extent instances of low composite-component strength

1.3.2 Narrow tolerances of the ceramic insert on account of press-connection

2 Idea of the invention:

2.1 Stud in a PE cavity

2.2 Ceramic insert with small amount of construction space being required (for example spherical structural form)

2.3 The fit of this stud can be realized as a function of the desired resistance-configuration (test results for press fit).

2.4 The stud can also be realized with an oval cross section in order, if applicable, to increase the resistance to rotation.

2.5 The spherical structural form can, if applicable, be replaced by another structural form.

3 Advantages of the invention:

3.1 Small amount of construction space required as a result of the spherical structural form and a short stud (approximately 2 mm)

3.2 High level of resistance to sudden change

The single figure shows a ceramic sandwich insert or acetabulum 1 which has a cover 2 of plastics material (PE) injection-moulded around it. The sandwich insert 1 has a spherical structural form and in accordance with the invention has at its end facing the metal shell, which is not shown, a stud 3 which projects into a cavity of the surrounding PE injection-moulding. The stud is approximately 2 mm long, this resulting in a

high level of resistance of the sandwich insert 1 to sudden change.

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VERIFICATION OF TRANSLATION

I, Lesley Marion Scarborough, of Redcliff Quay, 120 Redcliff Street, Bristol, England, am conversant with both the English and German languages and I state that, to the best of my knowledge and belief, the following is a true and correct translation of the official copy of the documents in respect of a patent application filed in Germany on the 8th January 2000 under Serial Number 100 00 521.7 and of the official certificate attached thereto.

Signature of translator L.M.Scarb

Dated this 3rd day of November 2003

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FEDERAL REPUBLIC OF GERMANY

Certificate of priority relating to the filing of a patent application

Serial Number: 100 00 521.7

Date of filing: 8th January 2000

Applicant/holder: CeramTec AG Innovative Ceramic Engineering, Plochingen/DE

Title: Ceramic sandwich insert for an artificial hip joint

Priority: 15.7.1999 DE 199 33 206.1

IPC: A 61 F 2/34

The attached copies are a correct and exact reproduction of the original documents of this patent application.

(*Seal*)

Munich, the 24th July 2000
On behalf of the President of
the German Patent and Trademark
Office
(*Signature*)
Hiebinger

Ceramic sandwich insert for an artificial hip joint

The invention relates to a sandwich insert having an inner ceramic sliding cup, which is surrounded by a plastics cover, for insertion into an outer metal shell of an artificial hip joint.

An artificial hip joint as a rule consists of a sliding cup which is inserted into an outer metal shell either directly or by way of a plastics cover. This metal shell is implanted in the pelvic bone. The combination of sliding cup and plastics cover is termed a sandwich insert.

A shaft, on which there is arranged a ball head that articulates in the sliding cup, is implanted in the femur.

In the case of artificial hip joints it is possible that the ball-head shaft will strike against the acetabulum time and time again. If the impact forces are sufficiently great, this can result in the mechanical acetabulum-composite breaking up. In particular, sandwich socket systems are at risk here, since the polyethylene (PE) that is predominantly used can only put up insufficient resistance against these forces of impact.

Sandwich inserts are produced in various ways.

In one system, the ceramic sliding cup or the insert respectively has plastics material injection-moulded around it, with recesses being arranged on the sliding cup. What is disadvantageous about this is the fact that the polyethylene (PE)-properties that result when

the same is heated are inferior. Furthermore, there is a thermal shock for the ceramic sliding cup. In addition to the outlay on injection-moulding on account of the injection mould and the handling of the hot portions, the large amount of construction space that is required is disadvantageous.

In the case of an alternative system, the sliding cup is anchored by a conical clamp in the plastics cover, with there being to some extent, instances of low resistance of the composite component. The disadvantage here as well is the large amount of construction space that is required.

The process of pressing the sliding cup into the plastics cover in the warm state is also preferably employed. In this connection, however, there occur to some extent instances of composite-component strength that are too low. Moreover, narrow tolerances must be observed on account of the press-connection.

The underlying object of the invention is to improve a sandwich insert in accordance with the preamble of claim 1 in such a way that a high level of resistance to sudden change is achieved with a small amount of construction space being required.

In accordance with the invention this object is achieved by the sliding cup having a stud at its outer end that is remote from the opening, whereby the resistance to sudden change is substantially increased, with a small amount of construction space being required, since the stud necessitates almost no increase in construction space.

Advantageously, the stud is arranged on the central axis or the axis of rotation of the sliding cup and has an axial length of 1 - 8 mm, preferably approximately 2 mm. This length suffices in order to increase the resistance to sudden change. However, other lengths can also be used.

In a preferred embodiment, the stud is arranged in the plastics cover by means of a fit. This can be an interference fit, a transition fit or a close clearance fit, depending on the desired resistance-configuration.

The stud can project completely through the plastics cover, project into it or else be surrounded at least in part by the plastics cover. It is preferably even completely surrounded by the plastics cover.

The cross section of the stud forms an n-sided body with n = 2, 4, 5 or 6. Alternatively, the cross section of the stud can even form a polygon or be oval.

The sliding cup is preferably of a spherical or a stepped structural form on its outside. Spherical structural forms require a very small amount of construction space.

In an advantageous embodiment, the plastics cover embraces the sliding cup at its open end.

The sandwich insert is preferably produced by pressing the sliding cup into the plastics cover.

Further features of the invention follow from the figures which are described in the following and in which

Figure 1 shows a sandwich insert in accordance with the invention in a spherical structural form;

Figure 2 shows a sandwich insert in accordance with the invention in a stepped structural form; and

Figure 3 shows advantageous configurations of the cross sections of the stud.

Figure 1 shows a sandwich insert having a sliding cup 1 of spherical structural form. During production, this sliding cup 1 is pressed into the plastics cover 2. The plastics cover 2 preferably consists of polyethylene (PE). The upper edge of the sliding cup is constructed so as to be flush with the upper edge of the plastics cover 2. In order to increase the resistance to sudden change, that is, also to anchor the sliding cup 1 in the plastics cover 2 in a better way, a stud 3 is arranged at the end of the sliding cup that is remote from the opening on the axis of rotation or central axis 4. This stud 3 projects into the plastics cover 2 in this embodiment.

Figure 2 shows an alternative embodiment with a stepped structural form for the sliding cup 1 on the outside thereof. Here, as well, a stud 3 is arranged on the central axis 4 and is completely surrounded here by the plastics cover 2. The axial length of the stud 3 is then approximately 2 mm.

In view of the fact that the sliding cup 1 is pressed into the plastics cover 2 during production, the stud 3 is inserted in the plastics cover 2 by means of a fit.

At its open end the plastics cover 2 embraces the sliding cup 1, thereby improving the securement. The collar 5 of the plastics cover 2 that rests on the upper side of the sliding cup 1 covers almost half of the upper edge.

Figure 3, by way of cross sections, shows the various configurations of the stud 3. In each case a cross section of the stud 3 is shown at right angles to the central axis 4.

Figure 3a shows an oval cross section for the purpose of increasing the resistance to rotation; Figure 3b shows a two-sided body; and Figure 3c shows a polygonal cross section. The latter has the advantage of being able to be produced by turning with a comparatively high level of removal of plastics material.

Figure 3d shows a four-sided or a square stud 3; and Figure 3e shows a five-sided body as a stud 3. Advantageously, also possible is a six-sided body for the stud.

Claims

1. Sandwich insert having an inner ceramic sliding cup (1), which is surrounded by a plastics cover (2), for insertion into an outer metal shell of an artificial hip joint, characterized in that the sliding cup (1) has a stud (3) at its outer end that is remote from the opening.

2. Sandwich insert according to claim 1, characterized in that the stud (3) is arranged on the central axis (4) of the sliding cup (1).

3. Sandwich insert according to claim 1 or 2, characterized in that the stud (3) has an axial length of 1 - 8 mm, preferably approximately 2 mm.

4. Sandwich insert according to one of claims 1 to 3, characterized in that the stud (3) is arranged in the plastics cover (2) by means of a fit.

5. Sandwich insert according to one of claims 1 to 4, characterized in that the stud (3) projects into the plastics cover (2) or projects completely through it.

6. Sandwich insert according to one of claims 1 to 4, characterized in that the stud (3) is surrounded at least in part by the plastics cover (2).

7. Sandwich insert according to one of claims 1 to 6, characterized in that the cross section of the stud (3) forms an n-sided body, preferably with n = 2, 4, 5 or 6.

8. Sandwich insert according to one of claims 1 to 6, characterized in that the cross section of the stud (3) forms a polygon.

9. Sandwich insert according to one of claims 1 to 6, characterized in that the cross section of the stud (3) is oval.

10. Sandwich insert according to one of claims 1 to 9, characterized in that the sliding cup (1) is of a spherical or a stepped structural form on its outside.

11. Sandwich insert according to one of claims 1 to 10, characterized in that the plastics cover (2) embraces the sliding cup (1) at its open end.

12. Sandwich insert according to one of claims 1 to 11, characterized in that the sliding cup (1) is pressed into the plastics cover (2).

Abstract

The invention relates to a sandwich insert having an inner ceramic sliding cup (1), which is surrounded by a plastics cover (2), for insertion into an outer metal shell of an artificial hip joint.

In order to increase the resistance to sudden change, whilst requiring little construction space, it is proposed that the sliding cup (1) has a stud (3) at its outer end that is remote from the opening.

(Figure 1)